

Centers for Disease Control and Prevention
Div. of Healthcare Quality Promotion
Attn: Resource Center
1600 Clifton Rd NE, Mailstop A-31
Atlanta, GA 30333

November 24, 2009

To Whom It May Concern:

Thank you for this opportunity to respond to the Centers for Disease Control and Prevention draft *Guidelines for the Prevention of Intravascular Catheter-Related Infections*. As a leading manufacturer of infusion therapy products, B. Braun Medical Inc. is dedicated to improving the delivery of healthcare and patient outcomes.

After a thorough review of the draft guidelines, B. Braun has made recommendations to the draft and urges the CDC to consider changing the guidance accordingly. The draft sections of most concern to our clinical and technical experts are:

- Replacement of Administration Sets
- Needleless Intravascular Catheter Systems.

Attached, please find B. Braun's response and clarification / correction recommendations.

Thank you, in advance, for your consideration.

Sincerely,



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Product Director
IV Systems Needleless Devices



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Enc. B. Braun Response
Needle Free Access Device Comparisons

B. Braun Medical Inc. Response to Centers for Disease Controls and Prevention Draft *Guidelines for the Prevention of Intravascular Catheter-Related Infections*
11-5-09 Publication

B. Braun Response to Needleless Intravascular Catheter Systems Recommendations

B. Braun recommends that the guidance emphasize proper practice when using needleless connectors and the need to disinfect all access devices properly regardless of design.

CRBSI rates are a multi-factorial issue and it has been shown they can be reduced through awareness, education, training, and good practice interventions.

We encourage the CDC to promote practice over product when discussing CRBSI and patient safety.

Key elements to address:

- Only 3 needleless connectors of the more than 15 available are used to represent all needleless mechanical valves
- The 3 products referenced in the studies are of similar internal design with interstitial fluid space. (entrapped areas where fluid may accumulate)
- 3 of the 4 supporting studies are specific to one product.
- Not all needleless connectors are designed the same; i.e., many do not have interstitial fluid space.

B. Braun Response to Replacement of Administration Sets Recommendations

Line 1044

1. In patients not receiving blood, blood products or lipid emulsions, replace administration sets, including secondary sets and add-on devices, no more frequently than at 96-hour intervals, [313] but at least every 7 days [255, 314-316]. Category IA

B. Braun recommends an indication that this should apply to continuous administration sets, secondary sets and add on devices that have been continuously connected to the primary administration set only. It is important to include discussion about tubing at time of IV catheter access/site change.

B. Braun recommends following the INS Standards of practice. Separately discuss Intermittent IV Administration sets including intermittent secondary set use and intermittent add-on device use.

Response to Needleless Intravascular Catheter Systems Recommendations

Line 1069

2. Change caps no more frequently than every 72 hours for the purpose of reduced infection rates or according to manufacturers' recommendations [328, 330, 333, 334]. Category II

Clearly define the word “cap” since the word “cap” in the medical lexicon refers to, for example, a cap that is used to maintain a sterile barrier at the end of an IV set or a needleless connector (valve). Efforts should be made to avoid confusion that may encourage single-use caps used for aseptic capping of IV lines to be reused over multiple days.

Line 1074

4. Minimize contamination risk by wiping the access port with an appropriate antiseptic (chlorhexidine preferred) and accessing the port only with sterile devices [330, 333, 335]. Category IA

B. Braun recommends the guidance include a clear definition of “wiping,” such as:

Antiseptic plus friction over time provides effective bacteria kill on connecting surfaces.

A mere “wiping” recommendation is open to interpretation which could leave out any of the above components and falls short of defining a best practice recommendation.

Line 1078

6. When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection [336-339]. Category II

This needleless connector recommendation is supported by four studies [336-339] that involve only 2 manufacturer’s needleless connectors. Three of the reference citations involve one specific device, Smartsite®Plus by Carefusion. The forth citation involves 2 ICU Medical devices; Clave® and CLC2000®. In sum these 4 studies compare devices that are somewhat similar but are not sufficient to represent all devices in this category due to significant internal and external design differences as discussed in lines 1119-1120.

B. Braun asserts that 4 studies of 3 valves of similar design are not representative of, nor sufficient enough to make a general statement about, all mechanical valve needleless connectors versus split septum.

Line 1087-1091

“Piggyback” systems are used as an alternative to stopcocks. However, they also pose a risk for contamination of the intravascular fluid if the device entering the rubber membrane of an injection port is exposed to air or comes into direct contact with nonsterile tape used to fix the needle to the port. Modified piggyback systems have the potential to prevent contamination at these sites [340].

The term “Piggyback systems” is confusing in this context. As it relates to IV administration, the word “piggyback” is a common term used to refer to an intermittent infusion delivered through the Y-site port on primary IV administration sets, also commonly referred to as a secondary infusion. In this context, B. Braun believes that the “piggyback systems” reference is being made to a Y-site and should be better defined.

B. Braun Medical Inc. Response to Centers for Disease Controls and Prevention Draft *Guidelines for the Prevention of Intravascular Catheter-Related Infections*

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1097-1099

Because of the large amount of space in the hub to accommodate the cannula, blood can easily backup into this space and occlude the catheter. A luer-activated device, which incorporates a valve preventing the outflow of fluid through the connector, was designed to eliminate this problem.

When and how can blood “easily back up into this space and occlude the catheter”?

All rubber membrane, split septum, and needleless connector valves prevent retrograde flow when not accessed. These are all normally closed devices when not accessed. When accessed, flow can be achieved in either direction for administration and aspiration. Therefore when accessed (open) and without continuous flow all of these devices will easily allow blood backup. It is not clear how any specific valve or split septum can eliminate this occurrence.

Line 1105- 1107

However, with the positive pressure the risk of occlusion may actually rise, as the valves are held open, allowing retrograde blood flow into the catheters.

All valves return to closed when the access is removed and help prevent any further retrograde flow into the catheter. Positive pressure valves, or more accurately termed “positive displacement” valves, are not held open when not in use so the risk of occlusion is no different with these devices. There is no citation to support this statement in the draft guidance. B. Braun is unaware of any literature that would support such a claim. Additionally, positive displacement devices provide a forward displacement of fluid through the catheter upon disconnection of a luer access. This fluid displacement is designed to prevent retrograde flow at disconnection and reduce the risk of occlusions.

In addition, Lines 1105-1107 appear to conflict with “support for reduction of occlusions from retrograde flow” as noted in lines 1111-1112.

Line 1108-1110

Many studies have shown that when the devices are used according to manufacturers' recommendations (i.e., appropriate disinfection prior to access), they do not substantially affect the incidence of CRBSI [328-335].

Yes this is true and conflicts with the recommendations of lines 1078-1079. B. Braun recommends that the CDC promote practice over product.

Line 1111-1114

Use of “second-generation” needleless connectors or positive pressure mechanical valves, which reduce the backflow of blood after it is disengaged, appear to be effective in reducing hub colonization in some [341-343], but not all studies [344]. In one study [341], the incidence of CRBSI was reduced when the needleless connector was compared to standard stopcocks.

Yes this is true, three citations [341-343] indicate that positive pressure mechanical valves reduce hub colonization; however this conflicts with the recommendations of lines 1078-1079.

Again the cited references in line 1079 do not provide sufficient enough evidence to make a general statement regarding all mechanical valve needleless connectors versus split septum based on the limited scope of valves that were cited in the references.

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In closing

Based on the varied reports both indicating concern and supporting the use of mechanical valves there is no firm conclusion to warrant recommendation for split septum over mechanical needleless valves.

What can be supported is that CRBSI rates are a multi-factorial issue and can be reduced through awareness, education, training, and good practice interventions as discussed in lines 1115 through 1117. B. Braun therefore encourages the CDC to determine, recommend, and promote best practice protocols which have clearly demonstrated a positive impact on patient safety by preventing catheter related infections.

Additional recommended resources demonstrating practice over product for best patient outcomes are:

Pronovost P, Needham D, et al. An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU. N Engl J Med 2006; Vol. 355 No. 26.

Muto C, Herbert C, et al. Reduction in central line-associated bloodstream infections among patients in intensive care units. JAMA, January 2006; Vol.295 No. 3.

Leone M, Dillon R. Catheter outcomes in home infusion. Journal of Infusion Nursing Mar/Apr 2008; Vol 31No 2.

Kaler W, Chinn R. Successful disinfection of needleless access ports: a matter of time and friction. JAVA Winter 2007; Vol 12 No 3.

Additional recommended reading:

Abe C, Zack J., et al. Zero tolerance: curbing catheter-related blood stream infections. Patient Safety & Quality Healthcare. Nov/Dec 2007.

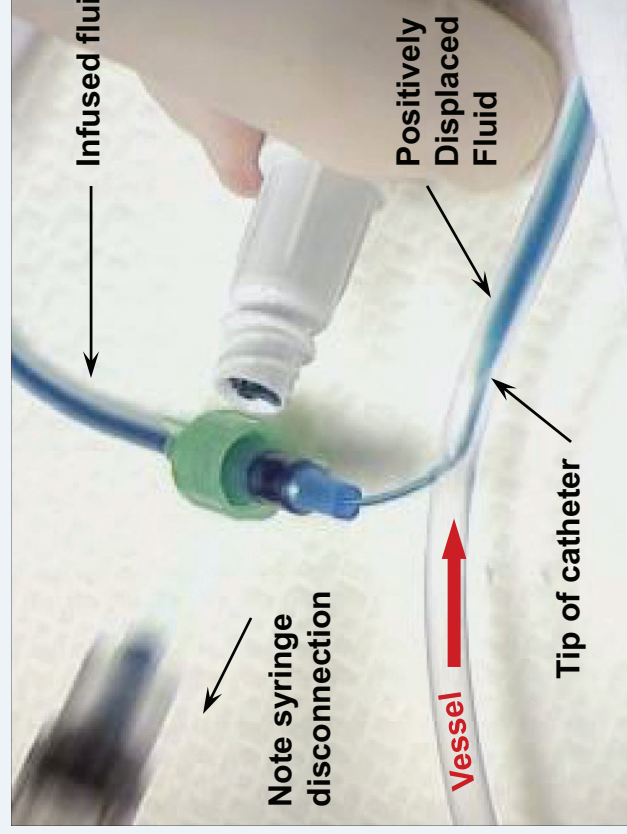
McGuire A. Zero infections, zero lost: Killeen's Metroplex Health System implements John's Hopkins initiative. Advance for Nurses, February 2009; Vol.7 No. 2.

Needle-Free Access Device Comparison

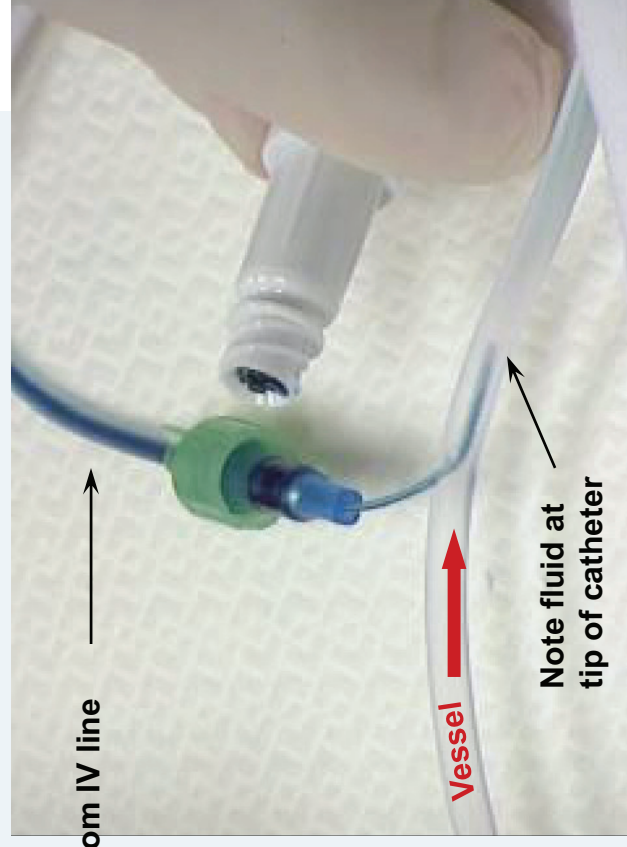
Positive Displacement–Luer Access Device

(Positive Displacement prevents drawback of fluid into the catheter during disconnection)

At Disconnection

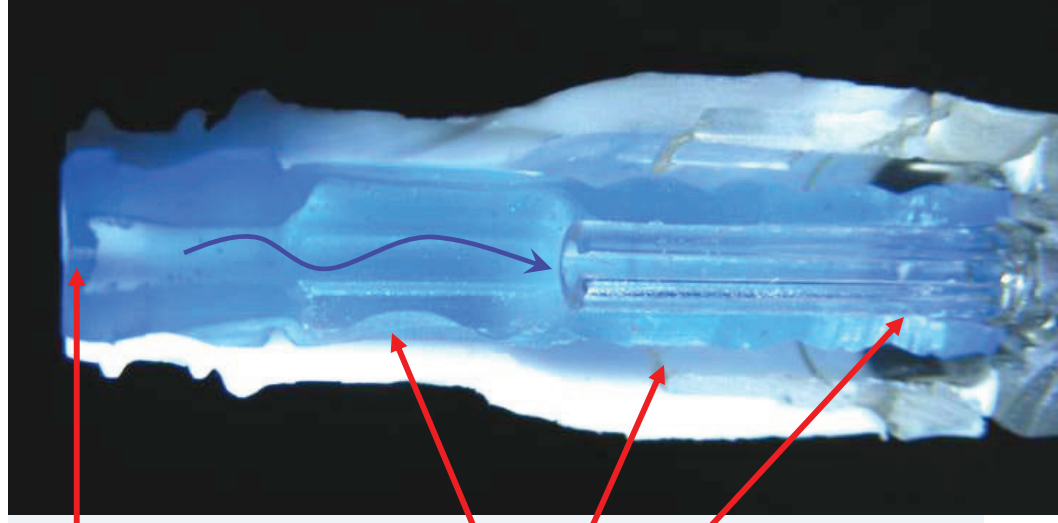


After Disconnection



Needle-Free Access Device Comparison

Device with Potential Internal Fluid Entrapment Areas
Smartsite® and Smartsite®-Plus



Seal

Potential entrapment Area

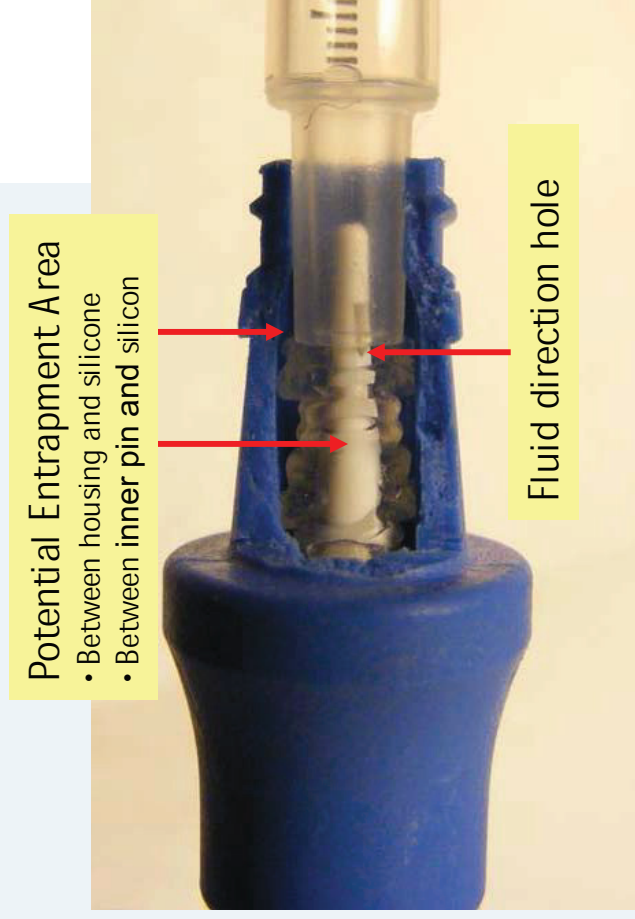
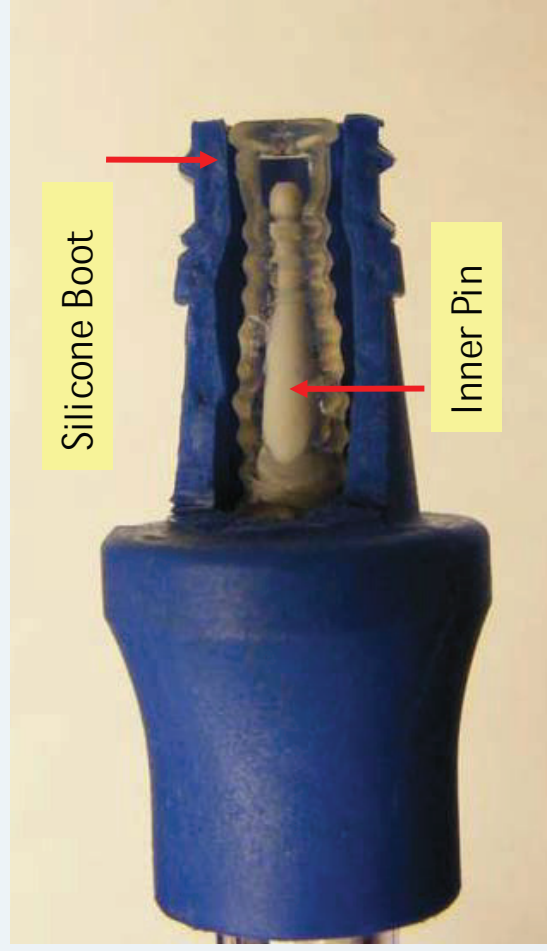
- Between housing and silicone
- Between inner pin and silicone



View through Male Luer at seal

Needle-Free Access Device Comparison

Device with Potential Internal Fluid Entrapment Areas Clave[®] valve cut-away section



Needle-Free Access Device Comparison

Device with Open Internal Fluid Pathway
ULTRASITE® valve cut-away section

